UNITED STATES DISTRICT COURT MIDDLE DISTRICT OF TENNESSEE NASHVILLE DIVISION

UNITED STATES OF AMERICA and the STATES OF TENNESSEE ex rel. JEFFREY H. LIEBMAN and DAVID M. STERN, M.D.	
Relators,	
v.)	Case No. 3:17-CV-00902
METHODIST LE BONHEUR HEALTHCARE, METHODIST HEALTHCARE-MEMPHIS	District Judge William L. Campbell, Jr. Magistrate Judge Barbara D.
HOSPITALS, THE WEST CLINIC, PLLC d/b/a WEST CANCER CENTER, WEST PARTNERS, LLC, LEE SCHWARTZBERG,	Holmes
M.D., ERICH MOUNCE, CHRIS MCLEAN,) GARY SHORB, AND JOHN DOES 1-100)	
Defendants.	

METHODIST DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF MOTION TO DISMISS THE SECOND AMENDED COMPLAINT

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PRELIMINARY STATEMENT

Methodist Le Bonheur Healthcare ("Methodist") is a Memphis-based, not-for-profit health system. West Clinic is a large, independent oncology practice group in Memphis. The University of Tennessee Health Science Center ("UTHSC") is the statewide, public, academic health system of the University of Tennessee ("UT"). In 2011, Methodist, West Clinic, and UTHSC entered into a seven-year affiliation to develop West Cancer Center to perform clinical care, academic training, and research services with the goal of becoming a National Cancer Institute-recognized program.

Under the affiliation, Methodist compensated West Clinic for its physicians providing clinical services and managing Methodist's oncology services program. Relators Jeff Liebman, the former CEO at one of Methodist's hospitals, and Dr. David Stern, the former Executive Dean of UTHSC, allege that the compensation Methodist paid West Clinic grossly exceeded fair market value for the services provided and was illegal remuneration intended to induce West Clinic physicians to refer patients to Methodist. Relators allege that the parties' arrangements violated the federal Anti-Kickback Statute ("AKS") and the Stark Law, and that Methodist's billing federal healthcare programs for services referred by West Clinic physicians violated the False Claims Act ("FCA").

Relators' Second Amended Complaint ("SAC") should be dismissed because Stern is not entitled to be a relator in this proceeding at all and, otherwise, the complaint fails to plead violations of the FCA in a manner that complies with Federal Rules of Civil Procedure 9(b) or 12(b)(6).

First, the FCA's "first-to-file" rule prohibits a new individual from joining an existing *qui* tam based on the same general facts as the pending action. Stern was not a relator when this lawsuit originally was filed but has joined as part of the Second Amended Complaint. Because Stern only alleges more facts about the same fraudulent scheme previously alleged by Liebman in the

Complaint and First Amended Complaint, Stern is barred from joining as a second relator, and the SAC he filed with Liebman must be dismissed.

Second, the SAC fails to plead that Methodist actually presented any false claims for payment to the government. Only the submission of false claims—not the alleged underlying violation of the AKS or Stark Law—triggers FCA liability. The Sixth Circuit requires that a relator plead at least one example of a false claim that was submitted for payment pursuant to any alleged fraudulent scheme. The SAC alleges none. Instead, Relators rely on inference and speculation to conclude that Defendants must have or ought to have submitted false claims for payment. Sixth Circuit precedent prohibits such speculative pleading.

Third, the SAC fails to plead the circumstances of the alleged fraud with sufficient particularity. At more than 500 paragraphs, the SAC is well-stocked with vignettes of conversations, emails, presentations, and negotiations, all colored by Relators' personal opinions and beliefs about the parties. The SAC is notably threadbare, however, with respect to the terms of the actual agreements, how or why payments made to West Clinic exceeded fair market value, or how Methodist executed allegedly "secretive" payments to West Clinic. Relators challenge the West Clinic physicians' "excessive" compensation, but do not provide a single physician's actual income. They claim Methodist paid "premium" rates for clinical services, but do not allege what those rates were. They say the West Clinic's management fees were "far higher than any legitimate fair market value," but provide no market value comparison. They say Methodist's investment in a cancer research company was "inflated," but rely exclusively on Stern's personal opinion. And, what money they admittedly cannot account for, Relators simply claim was paid in "secret" payments of unknown quantity and frequency to the tune of "tens of millions" of dollars. Such allegations simply do not plead AKS or Stark violations with particularity.

Because Liebman has amended his complaint twice and still fails to plead fraud with particularity in accordance with Federal Rules of Civil Procedure 9(b) and 12(b)(6), the SAC should be dismissed with prejudice.

BACKGROUND

I. Parties¹

Methodist Le Bonheur Healthcare is a not-for-profit health system in Memphis, Tennessee. (SAC ¶ 27.) Methodist Healthcare-Memphis Hospitals is a subsidiary of Methodist Le Bonheur Healthcare comprised of the health system's five hospitals. (*Id.* ¶ 28.) Collectively, these entities are hereafter referred to as "Methodist." Gary Shorb served as CEO of Methodist Le Bonheur Healthcare until retiring at the end of 2016. (*Id.* ¶ 38.) Chris McLean served as the CFO of Methodist Le Bonheur Healthcare until retiring at the end of 2018. (*Id.* ¶ 39.) These entities and individuals are collectively referred to as the "Methodist Defendants."

West Clinic, PLLC ("West Clinic"), is a private physician practice and a premier oncology practice in Memphis and surrounding areas. (Id. ¶ 29.) West Cancer Center is not a separate legal entity, but rather the publicly-used name of Methodist's oncology service line as jointly operated with West Clinic during the affiliation. (Id.) West Partners, LLC, is an entity affiliated with West Clinic, PLLC and used for business operations. (Id. ¶ 34.) 2

Relator Jeff Liebman served as the President and CEO of Methodist University Hospital from February 2014 until August 2017 (*Id.* ¶¶ 24-25.)

¹ The facts in this Memorandum are taken from Relators' SAC and are accepted as true for purposes of the Methodist Defendants' Motion to Dismiss.

² Relators additionally name one hundred unknown John Does as defendants who allegedly submitted or caused the submission of false claims. (Id. ¶ 40.) Relators allege these unnamed defendants are contractors, agents, partners, affiliated companies, affiliated entities, and/or representatives of one and another in submitting false claims. (Id.)

Relator Dr. David Stern joined UTHSC in 2011 as the Executive Dean and Vice Chancellor of Clinical Affairs. (*Id.* ¶ 18.) In addition to these and various other roles Stern held at UTHSC, he also served as Methodist's Executive Vice President of Medical Affairs until 2016 and served on Methodist's Board of Directors until 2017. (*Id.* ¶¶ 17, 21.) Stern was removed from his roles at the University in 2017. (*Id.* ¶ 21.)

II. Factual Background

In 2010, UT and Methodist began discussing developing a new academic cancer program with a focus on achieving designation as a National Cancer Institute ("NCI") Cancer Center.³ They executed a non-binding Memorandum of Understanding memorializing their commitment to this new oncology venture in July 2011, which was later superseded by an amendment to the parties' master affiliation agreement detailing the "guiding principles for the development of the premier academic-affiliated cancer program in the region...." (*Id.* ¶¶ 154-58.)

Methodist and UT were also in discussions with two Memphis-based oncology practices regarding a potential partnership to enhance the delivery of cancer care through the Methodist system's oncology service line. One of the practices was West Clinic, which in 2011 was providing physician services and outpatient cancer care at eight clinic locations in and around the Memphis area. 4 (*Id.* ¶ 30.) As discussions progressed into the summer of 2011, the parties formed a "Strategy

³ As noted in the SAC, "The National Cancer Institute (NCI) was created as part of the National Cancer Act of 1971. Through this program, NCI recognizes centers around the country that meet rigorous standards for research focused on developing new and better approaches to preventing, diagnosing, and treating cancer." (*Id.* ¶ 227 n.18.) A few NCI-designated Cancer Centers include: The Dana Farber / Harvard Cancer Center, Mayo Clinic Cancer Center, Memorial Sloan Kettering Cancer Center, St. Jude's Research Hospital, and The University of Texas MD Anderson Cancer Center.

⁴ Methodist had also been in discussions with the Boston Baskin Cancer Group d/b/a University of Tennessee Cancer Institute regarding a partnership to pursue NCI designation, though the parties could not come to terms, and discussions ended in late spring 2011. (*Id.* ¶ 140-141 n.10.)

and Partnership Model Steering Committee" comprised of representatives from Methodist and West Clinic, including Defendants Shorb, McLean, Mounce, and Schwartzberg, among others. (See id. ¶ 20.)

Methodist leadership wanted to increase its market share of cancer patients and considered a potential deal with West Clinic to be a "windfall" and "win-win" for everybody. (*Id.* ¶¶ 138, 146.) Methodist projected that West Clinic's referral of patients to Methodist would generate significantly higher revenues for Methodist. (*Id.* ¶ 142.)

Under the leadership of consultants from PricewaterhouseCoopers LLP ("PwC"), the committee met on several occasions in 2011, and the parties negotiated the structure and terms of their affiliation over several months before executing a series of agreements to jointly operate Methodist's cancer service line under the name West Cancer Center (referred to as the "Affiliation Agreements"). (*Id.* ¶ 167.) The agreed-to structure left the three entities independent in that the West Clinic physicians remained employees of the West Clinic, which contracted to perform services for Methodist and UTHSC, and which retained control over its individual physicians' compensation packages. (*Id.*) The Affiliation Agreements included:

- A **Professional Services Agreement ("PSA")** between Methodist and West Clinic under which Methodist paid West Clinic on a per wRVU basis for the professional clinical services performed by its physicians at Methodist's hospitals.⁵
- A Management Services Agreement ("MSA") (referred to in the SAC as a "Co-Management Agreement") between Methodist and West Clinic under which Methodist paid West Clinic management fees for assuming management responsibility for the health system's oncology service line.

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⁵ As explained in the SAC, "The most common measure of physician productivity is Work Relative Value Units (wRVUs). These units reflect the level of time, skill, training, and intensity of a physician to provide a given service. These units are the leading method for calculating the volume of work or effort expended by a physician in treating patients. Under this relative scale, a physician seeing two or three complex or high acuity patients per day would accumulate more RVUs than a physician seeing lower acuity patients each day." (*Id.* ¶ 139 n.9.)

- A Leased Employee and Administrative Services Agreement ("LEA") between Methodist and West Clinic under which Methodist leased West Clinic's administrative and non-clinical employees during the term of the parties' affiliation.
- An **Unwind Agreement** between Methodist and West Clinic detailing the terms and processes for unwinding the parties' affiliation.
- A Fourth Amendment to the Master Affiliation Agreement between Methodist and UT, establishing a three-way joint council responsible for coordinating the cancer program, and establishing an annual "Mission Support" payment from Methodist to UT to foster long-term growth and development of the cancer program.
- An **Affiliation Agreement** between UT and West Clinic designating West Clinic as UT's primary faculty group for the delivery of academically-related cancer care services and setting out faculty appointments and academic compensation packages for West's physicians from UT.

(*Id.* ¶¶ 157, 167, 178, 182.)

As a further investment in cancer research, Methodist also made a \$7 million investment in a cancer research company known as ACORN Research LLC (subsequently renamed Vector Oncology Solutions LLC, "Vector"), which was owned and operated in part by certain unnamed physician-members of the West Clinic. (*Id.* ¶ 274.) The investment was split equally between debt and equity. (*Id.* ¶ 374 n.21.)

Before setting the wRVU rates under the PSA or the management fee rates under the MSA, Methodist sought valuations from outside compensation consultants to determine their fair market value ranges. (*See id.* ¶ 403.) In addition, both the PSA and MSA contained schedules requiring the parties to periodically seek revaluations to identify the current fair market value ranges over the course of the parties' affiliation. (*See id.* ¶ 303.) During the first year of the affiliation, Methodist paid West Clinic \$34.6 million under the PSA and \$3 million under the MSA. (*Id.* ¶ 212.) As the parties continued to recruit new physicians and expand West Cancer Center's scope of services and specialties, the payments grew. In 2013, Methodist paid West Clinic \$36.7 million in wRVUs under the PSA and \$3.2 million for management services under the MSA. (*Id.* ¶ 213.)

In 2014, Methodist paid West Clinic \$38.4 million under the PSA and \$4.4 million under the MSA. (*Id.* ¶ 214.)

Relators allege that Methodist was overpaying West Clinic in order to buy their "340B business." (Id. ¶ 198.) They also allege that Methodist and West Clinic regularly monitored and tracked referrals from West Clinic to Methodist, which referrals increased—both inpatient and outpatient—during the term of the parties' arrangement. (Id. ¶ 277.)

The Affiliation Agreements were set to expire in December 2018, so in 2015 the parties formed a second "Strategy and Partnership Model Steering Committee" to begin discussing a potential extension and restructuring of the affiliation. (*Id.* ¶ 243.) The 2015 committee, like the 2011 version, was led by consultants from PwC and had representatives from Methodist, UTHSC, and West Clinic, including Defendants McLean, Shorb, Mounce, and Schwartzberg, and Relators Liebman and Stern, among others. (*Id.* ¶¶ 20, 250.) Also like the original group, the 2015 group met several times, with PwC's consultants interviewing numerous representatives from Methodist, West Clinic, and UTHSC regarding their impressions of the current affiliation and their goals for a potential extension and restructuring of the affiliation. (*Id.* ¶¶ 251-52.)

Relators allege that Methodist leadership withheld information relating to the financial performance of the cancer program and "intimidated" and "rebuffed" Relators when they attempted to raise questions about the cancer center and oncology service line. (*See id.* ¶¶ 193, 200.) Stern alleges that he repeatedly objected to payments to West Clinic physicians as inappropriate and excessive and that his complaints led to his being marginalized and eventually removed from the "inner circle" at Methodist. (*Id.* ¶¶ 193, 284.)

The parties continued discussions into the summer of 2016, when they began exchanging draft negotiating documents, including a memorandum drafted by West Clinic containing its

proposed terms and conditions of a new deal (referred to as the "Deal Points memo"). (*Id.* ¶ 293.) Some of the terms in the initial versions of the Deal Points memo included: (a) a commitment to developing a 5-year strategic plan, including a business plan, operating budget, and associated capital commitments for West Cancer Center; (b) a commitment by Methodist to continue reinvesting revenue from West Cancer Center back into its oncology service line; and (c) an agreement to continue periodically re-appraising the wRVU and management fee rates in accordance with the revaluation schedule in the current agreements. (*Id.* ¶¶ 297-303.) The Deal Points memo also provided that if the revaluation identified a new fair market value range for wRVUs, Methodist would agree to select the rates identified at the top end of that range. (*Id.*) The parties negotiated these terms and others throughout 2016, 2017, and 2018, but no agreement was ever reached and the parties unwound their affiliation after the Affiliation Agreements expired. (*Id.* ¶ 305.)

III. The 340B Drug Discount Program

A key aspect of the parties' pursuit of NCI-designation involved the 340B Drug Pricing Program ("340B Program"). The 340B Program allows certain healthcare entities that serve low-income and under-served areas to purchase pharmaceuticals at discounted prices. (*Id.* ¶ 7 n.3); *see also* 42 U.S.C. § 256b. Drug manufacturers who participate as a condition of Medicaid participation are required to sell certain outpatient drugs to these safety-net providers at reduced prices. (SAC ¶ 7 n.3.)

With Methodist participating in the 340B Program, the West Clinic locations that became cancer center sites also became eligible to participate as hospital-affiliated outpatient departments. (*Id.*) Before entering into the affiliation, the parties anticipated that enrolling the cancer center sites in the 340B Program would result in approximately \$15 million in 340B savings, which the parties sometimes referred to as the "lift" from the 340B Program. (*Id.* ¶¶ 143, 191.) The parties intended

to use these savings to fund cancer-related services, programs, and investments, including Methodist agreeing to create a "Mission Support Fund," often referred to as the "Lift Fund," to be paid to and administered by UT in order to foster long-term growth of the Cancer Program. (*Id.* ¶¶ 156-58.) Relators allege that instead of increasing Lift Fund payments to UT as 340B savings grew beyond what the parties originally projected, Methodist instead used the savings realized from its participation in the 340B Program, which they characterize as "profits," to pay West Clinic unlawful kickbacks. (*Id.* ¶ 160.)

IV. Procedural Background and Statement of Claims

Liebman filed this lawsuit under seal on May 31, 2017. (Dkt. No. 1.) Stern was originally not a relator. On May 24, 2018, Liebman filed a First Amended Complaint ("FAC"). (Dkt. No. 20.) On September 3, 2019, following a more than two-year investigation, the United States and the State of Tennessee filed notices that they were not intervening in the lawsuit. (Dkt. Nos. 44, 45.)

On December 10, 2019, before the lawsuit was unsealed, Liebman filed a motion for leave to file the SAC which added Stern as a relator and otherwise "streamline[d]" the litigation by dropping large portions of the FAC. (Dkt. Nos. 56-57.) The Court granted the motion to amend on December 12, 2019, and the SAC was filed on December 13, 2019. (Dkt. Nos. 58-59.) On December 19, 2019, the lawsuit was unsealed. (Dkt. No. 61.)

The SAC states six counts against all Defendants. Count I alleges Defendants presented false claims for payment in violation of the FCA and analogous Tennessee Medicaid False Claims Act ("TMFCA"). 31 U.S.C. § 3729(a)(1)(A); Tenn. Code Ann. § 71-5-182(a)(1)(A). Count II alleges Defendants violated the FCA and TMFCA by using false statements material to a false or fraudulent claim. 31 U.S.C. § 3729(a)(1)(B); Tenn. Code Ann. § 71-5-182(a)(1)(B). Count IV alleges violations of the same provisions, relying on express and implied false certification

theories. Count III alleges that all Defendants conspired to violate the FCA and TMFCA. 31 U.S.C. § 3729(a)(1)(C); Tenn. Code Ann. § 71-5-182(a)(1)(C). Counts V and VI allege Defendants knowingly retained an overpayment or avoided a payment obligation. 31 U.S.C. § 3729(a)(1)(G); Tenn. Code Ann. § 71-5-182(a)(1)(D).

The Methodist Defendants move for dismissal of all claims.

STANDARD OF REVIEW

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim for relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). While courts generally accept factual allegations in a complaint, the court need not accept as true legal conclusions. *Id.* To satisfy Federal Rule of Civil Procedure 8, a plaintiff must plead sufficient "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* But, "[a] pleading that offers labels and conclusions or a formulaic recitation of the elements of a cause of action will not do." *Id.* (internal quotation marks omitted).

Claims made pursuant to the FCA also must satisfy the heightened pleading standard of Federal Rule of Civil Procedure 9(b), which requires that a plaintiff "must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b); see also Universal Health Servs., Inc. v. U.S. ex rel. Escobar, 136 S. Ct. 1989, 2004 n.6 (2016). To meet this heightened burden, a qui tam relator must state "the who, what, when, where, and how of the alleged fraud." U.S. ex rel. Roycroft v. Geo Grp., Inc., 722 F. App'x. 404, 406 (6th Cir. 2018). Where relators bring claims against multiple defendants, they must make specific allegations as to each defendant's alleged involvement in fraudulent conduct. Hamm v. Wyndham Resort Dev. Corp., 2019 WL 6273247, at *4 (M.D. Tenn. Nov. 25, 2019).

<u>ARGUMENT</u>

Relators' SAC is materially deficient in both substance and process. As to process, it is barred by the FCA's first-to-file bar, which prohibits any party except the Government from intervening in a pending *qui tam* litigation. Stern has attempted to intervene in this case by joining Liebman in the filing of the SAC. His intervention is barred and requires dismissal of the SAC. As to substance, the SAC fails to state its claims of fraud with the particularity required by Federal Rule of Civil Procedure 9(b) in two equally fatal ways: first, it fails to plead facts showing any false claims were actually presented to the government for payment; and second, it fails to plead facts showing that any claims were "false," because it does not adequately plead violations of the federal AKS or the Stark Law. Each of these deficiencies is fatal in its own right and requires dismissal of the SAC.

I. RELATORS' SECOND AMENDED COMPLAINT MUST BE DISMISSED UNDER THE FCA'S FIRST-TO-FILE BAR.

The *qui tam* provisions of the FCA authorize private citizens to file civil actions on behalf of the United States and to receive a portion of any recovery. *See* 31 U.S.C. § 3730(d). However, to avoid duplicative lawsuits and "discourage opportunistic plaintiffs from bringing parasitic lawsuits whereby would-be relators merely feed off a previous disclosure of fraud," *Walburn v. Lockheed Martin Corp.*, 431 F.3d 966, 970 (6th Cir. 2005), the FCA provides that once a *qui tam* action has been filed, "no person other than the Government may intervene or bring a related action based on the facts underlying the pending action." 31 U.S.C. § 3730(b)(5).6

Liebman originally filed this *qui tam* lawsuit on May 30, 2017. (Dkt. No. 1.) Stern was not a party to the case at that time nor during the two-plus years that the government investigated the

⁶ The TMFCA contains an analogous bar, and the Relators' state law claims should likewise be dismissed. Tenn. Code Ann. § 71-5-183(e)(1).

allegations. On September 3, 2019, the United States and the State of Tennessee filed notices that they were not intervening. (Dkt. Nos. 44 and 45.) That same day, Liebman filed a motion requesting the Court to keep the lawsuit under seal to give him time to file a SAC that would "significantly narrow" the lawsuit. (Dkt. No. 46.) Liebman noted that the Complaint and FAC had "present[ed] two major claims: (1) the Methodist Defendants' payments to West Clinic physicians violated the AKS and Stark law, and (2) the Methodist Defendants' payments to many employed physicians violated Stark laws." (*Id.* at 6.) Liebman intended to file a SAC that would "discontinu[e] the claims against the Methodist Defendants regarding their compensation arrangements with employed physicians" and, instead, would "narrow the claims to focus on the financial arrangement between Methodist and West Clinic." (*Id.* at 3.) On September 20, 2019, the Court granted Liebman's motion and ruled that the case would remain under seal until December 16, 2019. (Dkt. No. 48.)

On November 15, 2019, Liebman filed a motion requesting leave to disclose the Complaint and FAC to Stern "for the purpose of potentially adding Stern as a Co-Relator in this case." (Dkt. No. 51.) The Court granted this motion on November 22, 2019. (Dkt. No. 54.)

On December 10, 2019, Liebman filed an "unopposed" motion for leave to file a SAC to "streamline" the litigation. (Dkt. Nos. 56-57.) Liebman argued that Stern was not barred as a relator under the FCA's first-to-file bar because the amendment was being done "by agreement" with Stern, Stern would add "extensive new allegations," and Stern would add claims against four individual defendants. (Dkt. Nos. 57 at 12-14.) The motion was "unopposed" given that the case was still under seal and proceeding *ex parte* with respect to Defendants. The Court granted the motion to amend on December 12, 2019, (Dkt. No. 58), and the SAC was filed on December 13, 2019. (Dkt. No. 59.) The case was unsealed and became public one week later. (Dkt. No. 61.)

The text of the FCA bars intervention in pending *qui tam* cases, and the Supreme Court has held that the only way a non-party can become a party to an FCA case is through intervention. *See U.S. ex rel. Eisenstein v. City of New York*, 556 U.S. 928, 933 (2009). Thus, although Stern did not file a motion to "intervene," he is prohibited from entering the lawsuit through an amended complaint. *See Fry*, 2006 WL 1102397, at *6 ("To find otherwise would permit any potential relator to circumvent the first-to-file doctrine by seeking entrance to the action via amended complaint, thereby undermining a central purpose of Section 3730(b)(5)-the preclusion of plaintiffs with merely duplicative claims."); *see also Health Choice Grp., LLC v. Bayer Corp., No.*, 2018 WL 3637381, at *11 (E.D. Tex. Jun. 29, 2018) (holding that "the FCA's first-to-file bar unambiguously bars" adding an additional relator through an amended complaint).

The first-to-file bar applies so long as the later complaint is "based in significant measure" on the same "core fact" or relies upon the same "general conduct" as the prior complaint. *U.S. ex rel. Poteet v. Medtronic*, 552 F.3d 503, 516 (6th Cir. 2009). And, it applies even if the later-filed complaint "incorporates somewhat different details." *Walburn*, 431 F.3d at 971; *see also U.S. ex rel. Branch Consultants v. Allstate Ins. Co.*, 560 F.3d 371, 378 (5th Cir. 2009) ("A relator who merely adds details to a previously exposed fraud does not help reduce fraud or return funds to the federal fisc because once the government knows the essential facts of a fraudulent scheme, it has enough information to discover related frauds." (internal quotations omitted)).

In this case, instead of adding new claims, by Relators' own admission, the SAC "significantly narrows" the claims in the FAC to focus only on the financial arrangements between Methodist and West Clinic. (Dkt. No. 46 at 3.) Relators acknowledge that Stern adds only "additional evidence material to the fraudulent schemes alleged in Relator's Complaint and First Amended Complaint." (Dkt. No. 51 at 3.) While Stern may allege additional factual details, those

details involve the same general conduct from the FAC that Methodist and West Clinic violated the AKS and Stark Law through a series of agreements in place from 2012-2018 involving clinical services, a management services arrangement, 340B drug profits, *and* the investment in Vector Oncology. (*See e.g.*, FAC ¶¶ 58, 77.) Based on those allegations, the SAC seeks recovery for the same identical six counts as the FAC. *Compare* FAC (Dkt. No. 20 at ¶¶ 309-349) *with* SAC (Dkt. No. 59 at ¶¶ 522-562).

Stern cannot avoid the first-to-file bar by naming additional defendants who were already implicated in the prior complaint. "[T]he fact that the later action names different or additional defendants is not dispositive as long as the two complaints identify the same general fraudulent scheme." U.S. ex rel. Armes v. Garman, 2016 WL 3562062, at *5 (E.D. Tenn. June 24, 2016) (quoting Poteet, 552 F.3d at 517). Shorb, McLean, Mounce, and Schwartzberg were all identified as leaders at the corporate defendants, if not deeply discussed and, in some cases, even quoted, in the FAC. (See e.g., FAC ¶ 68-70, 73, 107, 109, 222.) Individually naming them as defendants does not create a "materially different fraud allegation" that might survive the first-to-file bar. U.S. ex rel. Powell v. Am. Intercontinental Univ., Inc., 2012 WL 2885356, at *7-9 (N.D. Ga. July 12, 2012); see also U.S. ex rel. Hampton v. Columbia/HCA Healthcare Corp., 318 F.3d 214, 218 (D.C. Cir. 2003) (naming a subsidiary and a subsidiary's employees as defendants did not create "differences in the material elements of the fraud").

As such, Stern cannot join this existing *qui tam* matter through filing an amended complaint, and the SAC must be dismissed. See Fry, 2006 WL 1102397, at *4 ("[B]ecause the

⁷ Courts have divided as to whether the first-to-file bar acts as a jurisdictional bar. The growing trend of interpretations is that the first-to-file bar is not jurisdictional, particularly following the Supreme Court analyzing it as a non-jurisdictional issue after first addressing a non-jurisdictional statute of limitations issue. *See United States v. Millenium Labs., Inc.*, 923 F.3d 240, 248-51 (1st Cir. 2019) (citing *Kellogg Brown & Root Servs., Inc. v. U.S. ex rel. Carter*, 575 U.S. 650 (2015));

four new claims identified by [Relator 2] are, by [Relator 1]'s own characterization, just simply details of the fraudulent scheme already alleged by [Relator 1] in his Original and First Amended Complaint, [Relator 2] is jurisdictionally barred by the first-to-file bar from joining in this action as a second relator."); see also U.S. ex rel. Little v. Triumph Gear Sys., 870 F.3d 1242, 1245 (10th Cir. 2017) (dismissing amended complaint that named new relators and removed the original relator).

II. RELATORS FAIL TO PLEAD THEIR CLAIMS WITH SUFFICIENT PARTICULARITY UNDER RULE 9(B).

A. Count I Must Be Dismissed.

The FCA imposes civil liability for "knowingly presenting. . .a false or fraudulent claim" to the government "for payment or approval." 31 U.S.C. § 3729(a)(1)(A). To prevail on an FCA claim under (a)(1)(A), a relator must show: (1) **presentment** to the government, (2) of a **false or fraudulent** claim, (3) with **knowledge** of the claim's falsity, (4) that is **material** to the government's decision to pay the claim. *Id.*; *Universal Health Serv., Inc. v. U.S. ex rel. Escobar*, 136 S. Ct. 1989, 1996 (2016). Because FCA suits accuse defendants of fraud against the government, allegations of a claim's "presentment" (prong 1) and its "falsity" (prong 2) must be

U.S. ex rel. Bernier v. Infilaw Corp., 347 F. Supp. 3d 1075, 1081-83 (M.D. Fla. Nov. 8, 2018) (collecting cases). Though the Sixth Circuit has not addressed whether the first-to-file bar is still considered jurisdictional, it is not determinative of the ultimate outcome: the SAC must be dismissed under the first-to-file bar, either under Rule 12(b)(6) or under Rule 12(b)(1). *C.f. U.S. ex rel. Advocates for Basic Legal Equality, Inc. v. U.S. Bank, N.A.*, 816 F.3d 428, 433 (6th Cir. 2016) (affirming dismissal pursuant to the public disclosure bar under Rule 12(b)(6) rather than Rule 12(b)(1) following amendment of the public disclosure bar's jurisdictional language).

⁸ In addition to their claims under the FCA, Relators allege Defendants violated the Tennessee Medicaid False Claims Act's ("TMFCA") analogous provisions. Because Relators have failed to plead violations of the FCA, their TMFCA claims must also be dismissed. *See Dennis*, 2013 WL 146048, at *6, 17-18 (finding relator's failure to adequately plead violations of § 3729(a)(1)(A) fatal to his TMFCA claims, which were "analogous" and "co-extensive" with those asserted under the FCA).

pleaded with particularity under Rule 9(b). *U.S. ex rel. Dennis v. Health Mgmt. Assocs.*, Inc., 2013 WL 146048, at *11 (M.D. Tenn. Jan. 14, 2013); *see also U.S. ex rel. Bledsoe v Cmty. Health Sys.*, Inc., 501 F.3d 493, 504-510 (6th Cir. 2007) (holding that relators must plead both the fraud and examples of specific false claims pursuant to that conduct to avoid dismissal).

Relators' SAC fails to state a claim because it does not plead the required details of either prong. First, as to presentment, the SAC does not identify any false claim that was actually submitted to federal healthcare programs as a result of the parties' alleged violation of the AKS and the Stark Law. Second, as to falsity, the SAC does not allege with sufficient particularity that the Methodist Defendants violated the AKS or the Stark Law.

1. Count I Must Be Dismissed Because Relators Fail To Plead the Presentment of Any False Claims to the Government.

The SAC fails to plead that any false claims actually were submitted to the government for payment even though false claims are the "sine qua non" of an FCA violation. Sanderson v. HCA-The Healthcare Co., 447 F.3d 873, 878 (6th Cir. 2006). The FCA "attaches liability, not to the underlying fraudulent activity or to the government's wrongful payment, but to the claim for payment." Id. (internal quotation omitted). As such, Sixth Circuit precedent demands that relators connect their allegations of a fraudulent scheme to detailed allegations that, as a result of the scheme, claims actually were submitted to the government for payment. Chesbrough v. VPA, P.C.,

⁹ For all Relators' claims, the SAC does little to distill which allegations are directed at which of the four Methodist Defendants. Rule 9(b) "does not allow a complaint to merely lump multiple defendants together but requires plaintiffs to differentiate their allegations when suing more than one defendant and inform each defendant separately of the allegations surrounding his alleged participation in the fraud." *United States v. Corinthian Colls.*, 655 F.3d 984, 997-98 (9th Cir. 2011) (citation omitted); *see also U.S. ex rel. Ahumada v. NISH*, 756 F.3d 268, 281 n.9 (4th Cir. 2014) (refusing to even consider "undifferentiated allegations" made against certain defendants "as a group"); *U.S. ex rel. Bledsoe v. Cmty. Health Sys., Inc.*, 342 F.3d 634, 643 (6th Cir. 2003) ("[E]ach defendant named in the complaint is entitled to be apprised of the circumstances surrounding the fraudulent conduct with which he individually stands charged.").

655 F.3d 461, 472 (6th Cir. 2011) (imposing a "strict requirement" on relators to "identify actual false claims" to survive dismissal). "The mere allegation that a defendant violated the AKS . . . does not create FCA liability unless the defendant knowingly submitted claims that falsely certified compliance . . . [and] such compliance was a prerequisite to payment." *Dennis*, 2013 WL 146048, at *12. If a relator is not able to identify an actual false claim that was submitted, the Sixth Circuit has recognized limited circumstances under which a relator may satisfy the presentment element by "alleg[ing] specific personal knowledge that relates directly to billing practices" creating a strong inference that a defendant actually submitted false claims. *See U.S. ex rel. Prather v. Brookdale Senior Living Communities, Inc.*, 838 F.3d 750, 769 (6th Cir. 2016).

Where, as here, FCA claims are predicated on an alleged AKS or Stark violation, relators must identify a false claim arising from the alleged unlawful financial relationship. *U.S. ex rel. Hirt v. Walgreen Co.*, 846 F.3d 879, 881 (6th Cir. 2017); *U.S. ex rel. Suarez v. AbbVie Inc.*, 2019 WL 4749967, at *10-12 (N.D. Ill. Sep. 30, 2019) ("Where a relator's FCA claim depends on violations of the Anti-Kickback statute, the relator must identify a link between the alleged kickback and a claim for government payment."); *U.S. ex rel. Armes v. Garman*, 2016 WL 3562062, at *7-8 (E.D. Tenn. June 24, 2016) ("Noticeably absent from the Complaint is any specific allegation identifying a particular patient who received kickback-tainted care and the presentment of a claim to the government regarding that care. In the Sixth Circuit, alleging the details of a scheme is not enough; a representative sample is required."). And, a relator "must satisfy Rule 9(b)'s particularity requirement as to each element and *each defendant*." *Emmet v. Del Franco*, 2017 WL 697049, at *6 (E.D. Mich. Feb. 22, 2017) (emphasis added).

The SAC does not identify any representative false claim that actually was submitted to the government. Relators fail to identify a single patient for whom a claim was submitted to the government, or which West Clinic physician referred the patient, or what procedure or treatment any patient received that was billed to the government, or a date on which any such service was provided or billed to the government, or what reimbursement Methodist allegedly sought for any claim that was tainted by an improper referral. *Cf. Garman*, 2016 WL 3562062, at *7. The SAC alleges *none* of the relevant details comprising a representative false claim, falling woefully short of their pleading requirement.¹⁰

Instead, Relators make generalized allegations relating to Medicare reimbursement such as "the Medicare and Medicaid Programs covered the majority of patients at Methodist and West Cancer Center," (SAC ¶ 457) or, "[t]he Medicare claims data confirms a dramatic increase in referrals to the Methodist system" due to the alliance with West Clinic. (*Id.* ¶ 468.) Such allegations amount to speculation that Methodist *must have* submitted false claims as a result of the alleged fraudulent scheme. That type of inference cannot establish the presentment of a false claim under Rule 9(b). *See Sanderson*, 447 F.3d at 878 ("Rule 9(b) requires a *qui tam* plaintiff to do more than merely charge that the defendants engaged in fraudulent schemes that were 'pervasive and wide-reaching in scope' and then 'argue[] that the defendants must have submitted fraudulent claims' to the government.") (citation omitted).

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¹⁰ This is particularly true as to Shorb and McLean individually, as the SAC makes no allegations about either individual Defendant's role in the presentment of a false claim for payment. *See Emmet*, 2017 WL 697049, at *6 (holding vague allegations about each defendants' conduct fell "woefully short of Rule 9(b)'s specificity requirements"). And even more so as to the unnamed John Doe defendants, as to whom Relators make no attempt at all to plead any particular facts as to how such unnamed and unknown defendants submitted or caused the submission of false claims. *Id.; Silverstein v. Percudani*, 422 F. Supp. 2d 468, 473 n.3 (M.D. Pa. 2006) ("Plaintiffs have advanced no allegations against the John Doe defendants. They have not identified what actions the John Doe defendants took, or even their role in the scheme. Such a use of fictitious party pleading runs afoul of Rule 9(b), and we will dismiss these entities.").

Relators cite net patient revenues identified in Methodist's cost reports over the years and generally describe that Methodist's "other net income" increased during the affiliation, but pleading an increase in revenues does not satisfy Relators' requirement to plead the presentment of false claims. (SAC ¶¶ 485, 489.) Likewise, neither Exhibits A or B to the SAC, which list Methodist's Medicare Cost Reports and the total number of ICD-9 outpatient codes, including oncology codes, submitted by Methodist from 2008 to 2015 can be considered a representative example for purposes of Rule 9(b). *See e.g., U.S. ex rel. Ibanez v. Bristol-Meyers Squibb Co.*, 874 F.3d 905, 915-20 (6th Cir. 2017) (explaining that in order to satisfy Rule 9(b)'s pleading requirements, relators must adequately allege, from start to finish, each step in the chain of causation ultimately ending in the submission of a false claim to the government.)

Nor can Relators establish a strong inference that false claims were submitted through personal knowledge of Methodist's billing practices. The SAC does not allege that Relators have any such knowledge, much less the level of personal knowledge required to establish the presentment of false claims in accordance with Rule 9(b). *Id.* at 915-916 (holding that to meet the narrow personal-knowledge exception, a relator must plead firsthand knowledge of the defendants' billing practices or contracts with the government.) Because Relators failed to plead the quintessential element of an FCA violation—that claims actually were submitted to the government for reimbursement—the SAC must be dismissed.¹¹

2. Count I Must Be Dismissed Because Relators Fail to Plead an Underlying AKS or Stark Law Violation.

Under the FCA, a claim is "legally false" if a claimant falsely certifies compliance with a statute or regulation, and compliance with that statute is material to the government's payment

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¹¹ As described in more detail *infra*, Relators' failure to allege presentment of a representative false claim similarly dooms their claims under § 3729(a)(1)(B), (C), and (G).

decision. *Escobar*, 136 S. Ct. at 1995. Here, Relators claim Methodist falsely certified compliance with the federal AKS and Stark Law when submitting claims to government healthcare programs. To survive a motion to dismiss, Relators must plead sufficient factual allegations under Rule 9(b) to establish violations of one of those underlying statutes in order to plead the falsity of any claim submitted to the government. Fed. R. Civ. P. 9(b); *Dennis*, 2013 WL 146048, at *11-13.

a. Anti-Kickback Statute and Stark Law

The Stark Law generally prohibits a hospital from submitting a claim to Medicare for designated health services provided by physicians with whom the hospital has certain financial relationships. 42 U.S.C. § 1395nn(a)(1); 42 C.F.R. §§411.350-.389. Not every relationship is prohibited under Stark. Certain arrangements are exempt, including bona-fide employment, personal services, fair-market-value compensation, and indirect compensation arrangements, where enumerated conditions are met. 42 U.S.C. § 1395nn(e)(2), (e)(3); 42 C.F.R. § 411.357(l), (p). A common element among permissible arrangements is that the compensation provided to the physician does not exceed the fair market value of services performed. *See id.* § 1395nn(e)(2)(B)(i), (e)(3)(A)(v); 42 C.F.R. § 411.357(l)(3), (p)(1)(i).

The AKS is a criminal statute making it unlawful to offer or provide any remuneration to induce another to refer a patient for which payment may be made pursuant to a federal health care program. 42 U.S.C. § 1320a-7b(b)(2). Though not specifically defined by the AKS, Courts have interpreted remuneration to mean "something of value" or a "benefit" conferred from one party to another, *Bingham v. HCA, Inc.*, 783 F. App'x 868, 873 (11th Cir. 2019), and have held that in a business setting, whether a transaction confers a "benefit" from one party to another is determined by comparing the terms of a transaction to its fair market value. *Id.; see e.g. Jones-McNamara v. Holzer Health Sys.*, 630 F. App'x 394 (6th Cir. 2015) ("[T]he [AKS] defines 'remuneration' as 'transfers of items or services for free or for other than fair market value.""). Like the Stark Law,

the AKS also has "safe harbors" expressly excepting some arrangements from the statute altogether, which "closely parallel" the Stark Law exceptions. *Bingham v. HCA, Inc.*, 2016 WL 6027115, at *3 (S.D. Fla. Oct. 14, 2016), *aff'd sub nom. Bingham v. HCA, Inc.*, 783 F. App'x 868 (11th Cir. 2019).¹²

Here, Relators allege that Defendants violated the AKS and Stark Law because Methodist channeled revenue from the West Cancer Center to West Clinic physicians by paying for referrals and by paying them more than fair market value for services performed in the operation of the West Cancer Center from 2012-2018. But for each financial arrangement Relators place at issue, they fail to plead the details necessary to state a claim under the AKS, the Stark Law, or the FCA under Rules 9(b) and 12(b)(6).

b. Financial Arrangements at Issue

Relators claim the following transactions were improper under AKS and Stark: (1) the PSA between Methodist and West Clinic, (2) the MSA between Methodist and West Clinic; (3) Methodist's investment in Vector Oncology; and (4) Methodist's "sharing" 340B "drug profits" with the West Clinic physicians.¹³

Relators' allegations that Methodist violated AKS or Stark fail for two reasons. First, for each financial arrangement, they fail to identify either the details of the arrangement itself or its

¹² As the Eleventh Circuit explained in *Bingham*, the issue of fair market value is not limited to a defendant's safe harbor defense, "but rather something Relator must address" to make their claim. 783 Fed. App'x at 873; *see also U.S. ex rel. Rosenfeld v. Univ. of Miami*, 2018 WL 8581772, at *5 (S.D. Fla. Mar. 29, 2018) (explaining that in order to allege a Stark violation, relators must plead some benchmark of fair market value against which the defendants' compensation arrangements can be tested).

¹³ Relators' claims regarding these transactions are not so neatly defined, but are instead scattered loosely about the 562-paragraph SAC. Adding further to its length and confusion, Relators also periodically inject allegations regarding, among other things, free or discounted rent, altering of documents, and intentionally moving care away from vulnerable patient populations. Though plentiful, these allegations do not appear to relate to Relators' claims that Defendants violated

fair market value, or both. Without these factual allegations, Relators cannot state a claim under the FCA. *AbbVie, Inc.*, 2019 WL 4749967, at *10 ("Because Relator has not pleaded illegal remuneration. . .Relator's FCA claims necessarily fail.")

Second, Relators fail to allege particularized facts regarding any individual West Clinic physician, such as what that physician was paid, what services he performed, or whether the payments associated with the physician were above fair market value.

c. The SAC Fails to Plead an AKS or Stark Violation as to Any Financial Arrangement

(1) West Clinic Compensation under the PSA

Relators allege that Methodist overpaid West Clinic for the clinical services provided by the West Clinic physicians under the PSA, but the SAC offers no specific facts to adequately plead that Methodist paid West Clinic above fair market value. Indeed, despite Relators' senior executive positions at Methodist, and their alleged involvement in the operations of West Cancer Center, the SAC does not even include the actual terms of compensation to West Clinic under the PSA, much less any facts showing that the compensation actually paid to West Clinic or its physicians under the PSA exceeded fair market value.

Relators allege that Methodist and West Clinic entered into a PSA, effective December 31, 2011, which set the terms and rates for Methodist's payments to West Clinic for its physicians to provide clinical services. (SAC ¶ 167.) But Relators fail to plead what those terms and rates were. The SAC explains that wRVUs are "the most common measure of physician productivity" (*id.* ¶

AKS or Stark. (See SAC ¶¶ 63, 89 (describing the alleged AKS and Stark violations).) So, only these four transactions are addressed in this memorandum. And, they are done so independently and in order given that "[c]ourts are cautioned to construe false or fraudulent schemes as narrowly as necessary to protect the interest promoted by Rule 9(b)," and should "examine[] the specific allegations relevant to each individual scheme." U.S. ex rel. Richardson v. Lexington Foot & Ankle Center, PSC, 2018 WL 2709320, at *5 (E.D. Ky. June 5, 2018).

139 n.9), but does not allege the actual wRVU rates that Methodist paid to West Clinic. The SAC alleges that during a meeting in April 2011, Shorb and McLean told Stern the rate would be \$120 per wRVU (id. ¶¶ 139, 406), but the parties did not enter into a final arrangement until eight months later, and the SAC does not allege that \$120 was the final rate. Nor does it allege the actual rate paid by Methodist to West Clinic, or whether that rate applied to each West Clinic physician or varied by physician or subspecialty, or whether that rate changed during the parties' seven-year affiliation. ¹⁴

Rather than discussing the PSA's actual terms, Relators spill much ink discussing demands made by West Clinic during the parties' negotiations over an extension of the affiliation in 2016, such as West Clinic circulating a "Deal Points" memo demanding payments to West Clinic physicians at or above the 90th percentile compensation per wRVU. (*Id.* ¶ 303.) But, the parties did not end up extending the terms of their affiliation, so Relators' allegations regarding these demands cannot state a claim.

The SAC does include the aggregate amounts paid by Methodist to West Clinic under the PSA for 2012 through 2014.¹⁵ (*Id.* ¶ 212-14.) Yet, the SAC alleges no other facts by which to

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¹⁴ Even if Methodist did pay West Clinic \$120 per wRVU, the SAC does not allege facts establishing that such a rate was above fair market value for the services provided by these specific physicians. Relators allege that \$120 per wRVU was higher than the rate requested by UTCI (SAC ¶ 140) but do not indicate how that would make the rate requested by West Clinic above fair market value. Relators allege that Shorb and McLean "knew that West Clinic's higher rate per wRVU was above the Memphis market rates for oncologists" (*id.* ¶ 142), but the SAC does not indicate what the Memphis market rates were or how West Clinic physicians' rates compared to those rates.

¹⁵ Although Relators seek to hold Defendants liable for the entire duration of the parties' affiliation from 2012 through 2018, they include only minimal details from the PSA and MSA for 2012, 2013, and 2014 and no detail after 2014. Even if the details for 2012-2014 were adequately pleaded, which they are not, Relators cannot satisfy their pleading obligation for 2015-2018 merely by alleging that fraudulent conduct occurred in some years, so it must have occurred in others. *See e.g.*, *U.S. ex rel. Aryai v. Skanska*, 2019 WL 1258938, at *9 (S.D.N.Y Mar. 19, 2019) (dismissing such claims under Rule 9(b) as impermissible conjecture and hypothesis.) At the very least, Relators' claims relating to 2015 through 2018 must be dismissed.

assess whether the total payments exceeded fair market value for services performed, such as what clinical services were performed, how many wRVUs were completed, by how many physicians, at what wRVU rates, and for what sub-specialties. *Cf. U.S. ex rel. D'Annna v. Lee Mem'l Health Sys.*, 2019 WL 1061113, at *4 (M.D. Fla. Mar. 6, 2019) (noting that the relator's Amended Complaint identified specific physicians by name; specific compensation schemes; wRVU rates and amounts; internal and external audit reports indicating they exceeded fair market value; and specific methods used to inflate wRVU productivity, which were reported to senior management.) Nor do these allegations of total annual payments to West Clinic identify what Methodist actually paid to any single physician.

In sum, Relators allege payment demands made by West Clinic and payment rates that were discussed in negotiations, but they do not allege the actual payment terms reached between the parties. Nor do they make any allegations about the actual volume of work performed by any West Clinic physician or the group as a whole. While their allegations make for a long complaint, they lack the essential facts needed to allege with particularity that Methodist compensated West Clinic above fair market value for services performed by the West Clinic physicians.

(2) Management Fees Pursuant to the MSA

Relators allege that Methodist paid West Clinic "inflated" management fees under the MSA in excess of any "legitimate fair market valuation." (*Id.* ¶ 306, 373.) Relators again fail to provide specific facts to support that claim. Like the PSA, Relators allege the MSA was effective December 31, 2011, (*id.* ¶ 167), and it set the terms for West Clinic's management of the health system's oncology service line, including the fee schedule. As with the PSA, Relators provide the total payments made under this agreement for 2012, 2013, and 2014—\$3 million, \$3.2 million, and \$4.4 million, respectively. (*Id.* ¶ 212-14, 368-69.) Relators do not allege, however, what the fair market value for managing a service line of this size, scope, and specialty was during those

years. See e.g., Univ. of Miami, 2018 WL 8581772, at *5 (requiring allegations of benchmark fair market value against which the terms of the physician compensation agreement at issue can be compared). Relators allege only that the parties obtained a fair market value opinion before executing the MSA and that they "schemed of ways to exceed the valuation number." (Id. ¶ 171.) The SAC does not allege what that number was or how it compared to the \$3.0 million that Methodist paid under the MSA in 2012. And while the SAC ties these management fees to a percentage of the oncology service line revenue, it does not allege the how the payments owed under the MSA were determined or made. (Id. ¶ 368-69.)

Like the PSA, the MSA contained terms setting a schedule for periodic revaluations of its rates. (*See id.* ¶ 303 (noting this revaluation schedule).) Yet, the SAC does not reference any of those fair market value ranges either. In their place, Relators offer Liebman's opinion based on his experience as an executive at one of Methodist's five hospitals that the West Clinic did not fulfill all of its management obligations for the entire health system, and his conclusion that the fees Methodist paid to West Clinic *must have been* higher than any "legitimate" fair market value. (*Id.* ¶¶ 347-73.) This type of inference-based supposition does not satisfy the stringent pleading requirements of Rule 9(b).

(3) Vector Investment

Relators allege that Methodist "disguised" a kickback to the West Clinic's physicians by investing \$7 million in Vector Oncology—a cancer research company run by certain physician-members of the West Clinic. (*Id.* ¶¶ 9, 374.) Although the SAC discusses the company's post-investment operations and goals—which included providing specific, enumerated services to Methodist (*id.* ¶¶ 378, 385-87)—as well as Stern's personal views of the company, it provides no factual detail about the actual investment or its value. As with the MSA and PSA, Relators offer no factual allegations to show that this investment was in excess of fair market value. Relators

offer only Stern's repeated, conclusory opinion that there was "no legitimate business reason" for Methodist to invest in a cancer research organization when it was launching a new cancer center and his belief that Vector Oncology did not offer anything of "significant legitimate value" to Methodist or UT. (*Id.* ¶¶ 388-91.) Alleging that the services provided were not "unique" or "original" (*id.* ¶¶ 379, 385) does not establish that the investment was not made within the fair market value range for such investments.

Nor does Relators' allegation that approximately half of Methodist's investment was to pay off the "personal debts" of certain West Clinic physicians plead an AKS or Stark violation with particularity. Apart from repeating the claim several times throughout the SAC, (*id.* ¶ 9, 163, 374, 389), Relators offer no detail whatsoever regarding the transaction, such as how it was structured, what debts were satisfied as a result, to what creditors, in what amounts, how those amounts were excessive, or even which West Clinic physicians beyond Dr. Schwartzberg may have had their debts paid off. Relators' essential claim is that the investment did not make business sense or align with Methodist's "mission" in Stern's eyes. Rule 9(b) demands far more.

(4) 340B Drug Savings

Throughout the SAC, Relators allege that Methodist improperly "shared," "paid," and "distributed" millions of dollars in 340B savings generated from the West Cancer Center affiliation to West Clinic. (*Id.* ¶¶ 7, 8, 138, 144, 152, 216, 242, 409.) This repeated, conclusory claim is unsupported by any specific factual allegations as required by Rule 9(b). Courts have long held that to plead fraudulent conduct under Rule 9(b), plaintiffs must include all the details one would expect to find in the first paragraph of a newspaper article—that is, the "who, what, when, where, and how" of the purported fraud. *U.S. ex rel. Roycroft v. Geo Grp., Inc.*, 722 F. App'x 404, 406 (6th Cir. 2018). Yet here, Relators' allegations of "drug profit sharing" include no specific facts.

They do not identify *when* the payments were made, nor *how* they were made, nor in *what* amount they were made.

Relators allege that the parties initially projected Methodist would save \$15 million per year in chemotherapy infusion drugs and oral cancer medication at the new cancer center through its participation in the 340B Program. (*Id.* ¶ 143.) Early on, before the involvement of independent consultants and the formation of the joint Steering Committee, the parties discussed the \$15 million in savings benefiting them in equal amounts of \$5 million per year. (*Id.* ¶ 148.) When the transaction was later finalized, Methodist agreed to pay an annual "Mission Support" payment of \$5 million or one-third of the savings to UT to foster long-term growth of the cancer program. (*Id.* ¶ 158.) But when Methodist ended up saving more than \$15 million per year, it never paid UT more than the originally-discussed \$5 million. (*Id.* ¶ 159.)

Relators then infer that *because* Methodist never increased its Mission Support payments to UT, it *must* have split the rest of its 340B savings with the West Clinic rather than utilizing them to facilitate growth, improve care, and otherwise further West Cancer Center's mission. The SAC provides no specific facts to support that conclusion. It does not identify any "Mission Support" or "savings-sharing" agreement between Methodist and West Clinic that provided for such payments. Nor does the SAC allege *how* Methodist divided the remainder of its savings, *when* it made those purported 340B payments to West, *how* it made them, or in *what* amounts. In fact, Relators never put a dollar figure to the purported 340B payments, claiming only that they amounted to "tens of millions" of dollars. (*Id.* ¶ 216.)

Lacking any factual details about the alleged 340B payments to West Clinic, Relators claim simply and without explanation that Defendants "closely guarded the secrecy of [the 340B] payments" and "manipulated the accounting reports" to conceal them. (*Id.* ¶ 210, 292.) Those

allegations are as unsupported as the ones relating to the payments themselves, and they do not excuse insufficient pleading. Rule 9(b) demands that if a relator asserts a claim of *fraud*, he must state the circumstances of the fraud "with particularity." Fed. R. Civ. P. 9(b). Relying on a hunch that illicit payments must have existed but also claiming that they must have been kept secret falls well short of pleading fraud with particularity under Rule 9(b).

d. The SAC Fails to Plead Particularized Allegations Regarding Any Individual West Clinic Physician

The SAC is deficient under Rule 9(b) because it fails to plead particularized facts regarding any individual West Clinic physician. Despite the SAC running for 562 paragraphs, it is devoid of any reference to what compensation was paid to any individual West Clinic physician or what services were performed by any physician. Stunningly, the SAC does not even identify by name the actual physicians who comprise West Clinic. ¹⁶ It states only that in 2011 the West Clinic was comprised of 27 physicians from four subspecialties, including medical oncology, gynecological oncology, radiation oncology, and diagnostic radiology. (SAC ¶¶ 139, 398.) Thereafter, the SAC simply refers to "West Clinic physicians" in the aggregate, which is not sufficient for pleading violations of AKS or Stark with particularity.

The SAC alleges Methodist paid the West Clinic physicians' annual incomes "greatly exceed[ing] the MGMA national 90th percentile compensation" for their specialty but fails to identify a single West Clinic physician's income for any year or that physician's skill level, years

¹⁶ Relators allege generally that "The West Clinic oncologists" had ownership or investment interests in the West Clinic (SAC ¶ 81), but they fail to plead who those physicians were or what ownership stake they had. It is not enough for Relators to simply, and without support, claim that an entire group of defendants occupied a direct compensation relationship with Methodist through their ownership interests in the West Clinic, then fail to provide any detail regarding that ownership interest, or of the individual physicians' incomes, duties, skill, experience, productivity, or titles within the practice.

of experience, or productivity as compared to any type of benchmark for that physician. *Cf. Univ. of Miami*, 2018 WL 8581772, at *5 ("a growing contingent of district courts have found that, in order to allege a departure from fair market value, and thus a violation of the Stark Statute, 'Relator[s] must allege a benchmark of fair market value against which Defendants' [compensation arrangements with] physician[s] can be tested."") (quoting *U.S. ex rel. Osheroff v. Tenet Healthcare Corp*, 2012 WL 2871264, at *7 (S.D. Fla. July 12, 2012) and citing *Dennis*, 2013 WL 146048, at *13 (M.D. Tenn. Jan. 14, 2013)). ¹⁷

The SAC alleges that sometime in 2014 or 2015, either McLean or Shorb remarked to Stern that he believed West Clinic's "oncologists" generally earned \$1 million per year and "senior oncologists" earned \$3 million per year. (*Id.* ¶ 400.) Again, that vague allegation fails to allege with particularity what any West Clinic physician actually was paid, how much of that income came from Methodist, ¹⁸ what services that particular doctor performed, or what the fair market value compensation for the particular physician should have been. It fails to even identify who were the "oncologists" and who were the "senior oncologists." Put simply, Relators cannot satisfy their pleading obligations by pleading generally that Methodist overpaid West Clinic's physicians without providing the payment details for any of the unnamed physicians at issue.

In sum, the SAC lacks the fundamental details relating to each of the four financial arrangements between Methodist and West Clinic to show that any payments were made in

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 $^{^{17}}$ Relators' bald citation to the self-reported medical oncology salaries listed in the MGMA data (SAC ¶ 401) do little to advance their cause. As explained *infra*, they have offered no details of any West oncologist's actual compensation, duties, skill, or productivity against which the numbers can be compared.

¹⁸ The SAC acknowledges that the doctors were not employees of Methodist but continued to operate as a private physician group. (*See, e.g.* SAC ¶ 29.) Additionally, the SAC notes that West Clinic had eight clinic sites, only five of which became part of the affiliation with Methodist. (*Id.* ¶ 30.) The SAC is silent regarding what compensation the West Clinic physicians received from activities not related to Methodist or how that impacted the physicians' total incomes.

violation of the AKS or Stark law. Additionally, the SAC does not allege particularized facts relating to any individual West Clinic physician that would allow assessment of whether payments for the services performed by that physician were not appropriate. As such, the SAC fails to plead the falsity of any claims submitted to the government and must be dismissed under Federal Rules of Civil Procedure 12(b)(6) and 9(b).

B. Counts II and IV Must Be Dismissed Because Relators Fail to Plead a False Record or Statement That Was Used To Receive Payment of a Claim.

To sufficiently plead a claim under 31 U.S.C. § 3729(a)(1)(B), a relator must plead with particularity that a defendant "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(B). Under Rule 9(b), a claim under § 3729(a)(1)(B) "must provide sufficient detail regarding the time, place and content of the defendant's allege[d] false statements and the claim for payment." *See Dennis*, 2013 WL 146048, at *17 (citing *Bennett v. MIS Corp.*, 607 F.3d 1076, 1100 (6th Cir 2010)). As explained above, Relators fail to identify a single false or fraudulent claim. That alone is fatal to Counts II and IV. *Id.* ("On that basis alone, the relator's second claim for relief is subject to dismissal.") Relators have not pled a false or fraudulent claim to which a false record or statement could be material.

Relators also fail to provide factual allegations supporting their claims under § 3729(a)(1)(B) as required by Rule 9(b). Although Relators attach the Cost Report Filing History for MHMH to the SAC, as indicated above, they do not allege any particular facts about the underlying Cost Reports, particularly how they were inflated or otherwise false. In fact, Relators concede that the "cost reports submitted to CMS . . . do not reveal" the alleged fraud in this case. (*Id.* ¶ 501.) Beyond the Cost Report Filing History, Relators do not identify any other allegedly false records or statements that Methodist used or made to the government, let alone allege any of

the required, specific facts about such a record or statement. *See Dennis*, 2013 WL 146048, at *17. Because Relators fail both to identify any false record or statement allegedly made to the government and to tie such a record or statement to any allegedly false claim for payment, their claims under § 3729(a)(1)(B) must be dismissed under Rule 9(b).

C. Count III Must Be Dismissed Because Relators Fail to Plead a Conspiracy to Submit False Claims.

Section 3729(a)(1)(C) imposes liability on those who conspire to violate the FCA. 31 U.S.C. § 3729(a)(1)(C). To plead an FCA conspiracy claim, a relator must allege "an unlawful agreement to have a false claim paid" and "at least one act performed in furtherance of the conspiracy" with the particularity required by Rule 9(b). U.S. ex rel. Prather v. Brookdale Senior Living Cmtys., Inc., 2015 WL 1509211, at *17 (M.D. Tenn. Mar. 31, 2015); see also U.S. ex rel. Farmer v. City of Houston, 523 F.3d 333, 343 (5th Cir. 2008). "[G]eneral allegations of a conspiracy, without supporting facts to show when, where or how the alleged conspiracy occurred, amount to only a legal conclusion and are insufficient to state a cause of action." Dennis, 2013 WL 146048, at *17. Similarly, allegations that merely demonstrate an ongoing business relationship will not suffice without facts that evidence an agreement or understanding to commit fraud. Cf. FC Inv. Grp. LC v. IFX Markets, Ltd., 529 F.3d 1087, 1098 (D.C. Cir. 2008).

The SAC does not plead an FCA conspiracy claim. First, Relators have not sufficiently pled any underlying false claim under any of the other subsections of § 3729. 31 U.S.C. § 3729(a)(1) (creating liability for any person who "conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G)"). That alone requires dismissal of Count III. See U.S. ex rel. Crockett v. Complete Fitness Rehab., Inc., 721 F. App'x 451, 459 (6th Cir. 2018) ("[Relator's] lack of specification as to the existence of any false claim also precludes her false-claims conspiracy count."); U.S. ex rel. Winkler v. BAE Sys., Inc., 957 F. Supp. 2d 856, 876 (E.D.

Mich. 2013) (holding that relator's failure to sufficiently plead a violation of § 3729(a)(1)(A) or § 3729(a)(1)(B) necessitated holding of failure to plead conspiracy claim).

Relators also make no particularized allegations regarding the alleged unlawful agreement between the parties beyond describing typical business negotiations and transactions arrangements. *Cf. FC Inv. Grp. LC*, 529 F.3d at 1098. Although the SAC is long on descriptions of meetings, conversations, and negotiations between business partners, it lacks any particularized facts about Methodist's agreement with another party to submit false claims to the government. Absent such allegations, Count III must be dismissed.

D. Counts V and VI Must Be Dismissed Because Relators Fail to Plead a Reverse False Claim.

Section 3729(a)(1)(G), known as the FCA's reverse false claims provision, imposes liability for any person who "knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government." 31 U.S.C. § 3729(a)(1)(G). An "obligation" under the FCA includes "the retention of any overpayment." 31 U.S.C. § 3729(b)(3).

The SAC fails to allege a reverse false claim. First, as noted above, the SAC does not plead the presentment of any false claim or the use of false records or statements with sufficient particularity. As with Relators' other claims, that failure requires dismissal of Relators' claims under § 3729(a)(1)(G). See U.S. ex rel. Rahimi v. Rite Aid Corp., 2018 WL 1744796, at *6 (E.D. Mich. Apr. 11, 2018).

Second, the SAC provides no factual allegations about any specific overpayment that Methodist received or obligation that it had to repay funds. Pleading a reverse false claim requires such facts. *See Crockett*, 721 F. App'x at 459 (dismissing claim for failure to specify "concrete"

obligation owed to the United States"); *Chesbrough*, 655 F.3d 461, 473 (6th Cir. 2011) ("The Chesbroughs have not identified in their complaint any concrete obligation owed to the government by VPA at the time an allegedly false statement was made. Rather, they merely allege that VPA is obligated to repay all payments it received from the government."); *U.S. ex rel. Ibanez v. Bristol-Myers Squibb Co.*, 2015 WL 1439054, at *10 (S.D. Ohio Mar. 27, 2015); *Prather*, 2015 WL 1509211, at *16.

In addition, Relators have not made any specific factual allegations about what fraudulent records, statements, or other conduct the Methodists Defendants made or engaged in to conceal or retain an overpayment or avoid an obligation, such as who did so, where or when they did so, or the content or nature of such a fraudulent record, statement, or other activity. *See Prather*, 2015 WL 1509211, at *16; *Dennis*, 2013 WL 146048, at *18. For all of these reasons, Counts V and VI must be dismissed.

Although Relators fail to plead all their claims with the particularity required under 9(b) as against Shorb and McLean, this deficiency is particularly acute with regard to their claims under § 3729(a)(1)(G). Relators must make specific allegations as to each defendant's alleged fraudulent conduct, and mere group pleading fails to meet Rule 9(b)'s specificity requirement. *See Hamm v. Wyndahm Resort Dev. Corp.*, 2019 WL 6273247, at *4 (M.D. Tenn. Nov. 25, 2019). Here, Relators plead no allegations as to how Shorb or McLean failed to return an overpayment or caused anyone else to do so.

CONCLUSION

The SAC suffers from numerous flaws requiring its dismissal. It is barred by the FCA's first-to-file bar. It fails to provide a representative false claim that actually was submitted to the government for payment. And, it fails to plead with the required particularity that the Methodist Defendants violated the AKS or Stark Law. Given these deficiencies, and that the SAC was filed

after the 2017 Complaint was already once amended, and Relator Liebman even improperly recruited a second relator, it should be dismissed with prejudice, as any further amendment would be futile.

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that a true and exact copy of the foregoing has been served on the following counsel today, March 9, 2020, via the Court's CM/ECF email notification system:

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